



**U.S. DEPARTMENT OF COMMERCE
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[Robert L. Lundak]

• 247,656

• 03-26-81

Before the Board of Appeals

MAILED

FEB 21 1984

Townsend & Townsend

GROUP 170

FOR APPELLANT

RECEIVED

APR 10 1984

Examiner's Answer

BOARD OF APPEALS

588-11

This is an appeal from the final rejection of claims 1 and 2, the only claim in the case. The appealed claims have been correctly reproduced on page 1 of appellant's brief. No claims are allowed.

Subject Matter

The appealed subject matter refers to a particular fusion partner used in the production of human - human hybridomas which has a thousand fold higher rate of fusion. The products secreted from

human - human hybindomas, ie. human monoclonal antibodies, are recognized as having great value commercially.

The Rejection

The sole issue in this case is whether the disclosure must be enabling as of the filing date or as of the issued date.

The specification is objected to and the claims are rejected under 35 USC 112 first paragraph as not being adequate so as to enable one of ordinary skill to make and use the claimed invention. The issue arose from a failure to have the claimed cell line deposited at an independent depository on or before the filing date. A deposit of the cells is considered absolutely essential for enablement. Accordingly, the total disclosure as of filing is not enabling. The Commissioner's decision 886 OG 638 requires the deposit to be made "no later than the effective filing date of the application". Applicants have petitioned to change the filing date to the deposit date of the cells. This petition was denied.

In all of the case law cited by appellant, the cells were deposited before the filing date. See In re Argoudelis 168 USPQ 99 (CCPA 1970) and Feldman V. Aunstrup 186 USPQ 108 (CCPA 1975). The examiner is not aware of any *published* decision where the cells were deposited after the filing date.

Even though the appealed claims relate to "modified" human cancer cells and hybrids produced therefrom rather than microorganisms the issues revolving around the deposit remain the same.

Appellant urges that the law does not require a deposit but only a written description. Appellant further urges that depositing the cells aids infringement by allowing the public to be capable of infringing the patent. Appellant also urges that the written specification alone is enabling and therefore a deposit is never needed. However, while the statutes do not require a deposit they do require a full and enabling disclosure. Without the claimed cells, the written record is not enabling. Unlike a device or a composition which may be described sufficiently that it can be made, the current state of the art does not enable one to "make" a human cell from raw materials. As for preparing the claimed cell from another human cell, it should be noted that the parent cell line has not been shown to be available to the public at the time of filing. A description of how to modify something which is not available cannot be considered enabling. See White Consolidated Industries, V. Vega Serno Control 218 USPQ 961, (CAFC 1983). In fact, the examiner has reason to suspect that the parent cell line was not available to the public at the filing date since the parent cell line was made by an employee of the assignee of

this application. Further, the parent cell line is currently the subject of another pending U.S. application which has the same assignee and the same attorney.

One of the reasons why the 103 rejection was dropped is that one would require more than routine experimentation to produce the claimed cell line. It should be noted that the method for preparing the claimed cell line from the parent cell line was finally rejected under 35 USC 103 and has been canceled. See the reasons given by both sides why the claims are patentable over prior art. Again note White V. Servo supra where 1½ to 2 man years of experimentation was considered unreasonable and the patent held invalid for failure to be enabling.

As for appellant's aiding infringement by allowing the the ability to infringe, this point is not relevant to the present ground of rejection.

While it is recognized that some patents involving cells do not require a deposit, in these cases specific cells are not required but rather any one of a large group of well known species. Note Tabuchi V. Nubel 194 USPQ 521 (CCPA 1977) where the particular strains were known and available prior to the foriegn filing date and mere routine experimentation is required to use them. However, this is not the instant fact pattern; the cells are not known, not available, and require more than routine experimentation to

make and use them. Furthermore, it is not even clear if anyone, including appellant, can repeat the method of producing the exact cell line as was discussed in the final rejection (page 4) of claim 3 under 35 USC 103, without a deposit.

Appellant's suggestions as to how to handle cases involving deposits has been noted. However, the Patent and Trademark Office lacks the laboratory facilities and supplies to properly maintain and/or test a specimen.

Appellants urge that the conditions of the deposit mentioned In re Argoudelis are not mandatory and were modified by the CCPA in the Feldman V. Aunstrup case. Appellants continue that "Aunstrup had failed to deposit a microorganism at a depository consistent with the requirements set forth in Argoudelis and MPEP 608.01(p)". This statement is both misleading and incorrect. The deposit of Aunstrup is in full compliance with the current MPEP 608.01(p). Further the significant difference between Aunstrup and Argoudelis is the national location of the depository.

The other issue decided is whether or not the deposit can remain secret and with restricted access as long as the application remains secret and with restricted access. These features are moot in the instant case since the issue of permanence and availability after issuance of a

patent is not the question. The issue is whether or not the disclosure needs to be enabling as of the filing date. Alternatively, the issue can be worded, does the disclosure need to be complete as of the filing date. By contrast both Aumstrup and Argoudelis deposited before the filing date. Therefore both Aumstrup and Argoudelis were enabling as of the filing date. Appellant did not deposit on or before filing and therefore is not enabling as of the filing date.

Appellants further urge that the disclosure need not be enabling as filed but rather only enabling at the issue date. In support of this argument, appellants cite In re Argoudelis supra and In re Hawkins, 179 USPQ 157 (CCPA 1973). In re Argoudelis has been discussed and distinguished above. In re Hawkins dealt with the issue of new matter and incorporation of foreign patents in the specification, not enablement and deposit of cells.

Appellant has argued extensively and presented numerous facts showing reduction to practice before the filing date. The question of reduction to practice is not being appealed. Likewise for the arguments concerning best mode. The rejection is based solely on enablement grounds.

Appellant also urges that since the cells were given to others and kept by them as well, the cells were "deposited". Appellant continues that the cells were kept in a "public" institution and implies that this is

sufficient to constitute an enabling deposit. However, this "public institution" is the assignee and the "others" are employees of the assignee. Further the specification states ATCC is the depository. If appellant's arguments are to have any merit at all, appellant needs to state that these other people are the depository and not A.T.C.C. since A.T.C.C. did not receive the cells until after the filing date. Note Commissioner's notice 886 O.G. 638 requirement #2 in this regard.

Appellants urge that the depository charges a fee and that the commissioner is not authorized to require such a fee. However, this is not an appealable issue since A.T.C.C. requires the fee not the Patent and Trademark Office, Further, the P.T.O. does not require applicant to use A.T.C.C. It should be noted that not all depositories require a fee. Specifically NRRL, operated by the USDA, does not currently require a fee.

Appellant has presented a variety of arguments requesting that the filing date should be changed. This matter has previously been petitioned and the petition denied. This issue appears not to be appealable to the P.T.O. Board of Appeals.

In conclusion, the nature of the invention requires a deposit of the new cell line to provide an enabling disclosure. The criteria for a proper deposit is

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set forth in MPEP 608.01 (p) C. Appellants' deposit of the cell line does not conform to these criteria and therefore the disclosure is not enabled. Accordingly, rejection is deemed proper and should be affirmed.

Any inquiry concerning this communication should be directed to John Edward Tarcza at telephone number 703-557-3032.

Respectfully Submitted

John E. Tarcza

Tarcza: dg

2-1-84

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Thomas G. Wiseman

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GROUP ART UNIT 172